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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/781,111      | 02/18/2004  | Rogier Receveur      | P0010926.00         | 1950             |

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| EXAMINER |
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BERTRAM, ERIC D

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3766

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| MAIL DATE | DELIVERY MODE |
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06/28/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                                 |  |
|------------------------------|-------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/781,111 | Applicant(s)<br>RECEVEUR ET AL. |  |
|                              | Examiner<br>Eric D. Bertram   | Art Unit<br>3766                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1 and 3-20 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Amendment*

1. The declaration filed on 6/12/2007 under 37 CFR 1.131 has not been considered because the declaration is unsigned.

### *Response to Arguments*

2. Applicant's arguments filed 6/12/2007 have been fully considered but they are not persuasive. Regarding the 35 USC 102(e) and 35 USC 103(a) rejections of claims 1 and 3-20, the applicant relied on the 37 CFR 1.131 declaration in order to remove Hunter as a proper reference. However these arguments are moot since the declaration is unsigned and, as a result, unconsidered by the Examiner.

3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., navigating a distal portion of a lead through a portion of a coronary sinus based on differing temperature of blood) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As stated in the previous Office Action, Claims 1 and 12 merely require a sensor that senses a physical parameter **relating** to a distinguishing characteristic, such that the characteristic comprises a temperature difference between the blood present within a right atrium and blood exiting from a coronary sinus. As described in the previous actions and below Hunter teaches sensing the temperature in the cardiac anatomy, and the temperature of the blood is clearly *related to* the distinguishing

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characteristic described in the claims. Therefore, the 35 USC 102(e) and 35 USC 103(a) rejections are still considered proper.

4. Finally, the applicant incorrectly stated that claims 16-20 were rejected as being unpatentable over Hunter in view of Haldeman. As stated in paragraph 14 of the previous Office Action, these claims were rejected as being unpatentable over Haldeman in view of Official Notice. The applicant's arguments are thus moot. Furthermore, since the applicant did not distinctly and specifically traverse the Examiner's use of Official Notice, it is taken as admitted prior art that the use of averaging values is notoriously old and well known in the art and would have been obvious to one of ordinary skill.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 5, 6, 8-12, 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunter. Hunter discloses a catheter 52 that is navigable within a cardiac anatomy for delivering a medical electrical lead (par. 0043 and 0063). Disposed on the catheter is a plurality of sensors 58, including pressure, optical, oxygen, temperature and electromagnetic sensors for sensing physical parameters (para. 0043 and 0067 and

0076). As shown in figure 1, the sensors are communicatively coupled with workstation 34, which inherently includes a processor. The workstation receives the physical parameters and manipulates them into navigational data (para. 0016 and 0049). The workstation is then communicatively coupled to a display 36, which displays navigational data relating to the sensors and the catheter (para. 0049). Hunter further discloses an imaging device 12 which provides patient image data that is displayed in association with sensed parameters, including from magnetic field sensors as well as physical parameters from the body such as temperature and pressure (para. 0049). By combining this information, one can receive visual direction and confirmation to an anatomical location.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter in view of Lesh. Hunter, as described above, discloses the applicant's basic invention with the exception of disclosing that the temperature sensors can be a thermistor or a thermocouple. Attention is directed to the secondary reference of Lesh, who discloses an implantable lead utilizing a temperature sensor comprising a thermistor or a thermocouple (Col. 5, lines 40-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use a thermistor or a thermocouple as a temperature sensor on an implantable lead since their use is old and well known in the art.

11. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter in view of Zanelli. Hunter, as described above, discloses the applicant's basic invention including outputting information to a physician. However, Hunter does not disclose that the output is audible in nature. Attention is directed to the secondary reference of Zanelli, which discloses that the use of visual and audio outputs increase

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the safety of an implantable system (Col. 10, lines 46-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Hunter by adding audio outputs in order to increase the safety of the system since the physician would not have to look at a screen to receive instructions, but could hear them while focusing on the procedure.

12. Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haldeman et al. (US 2005/0049510, hereinafter Haldeman) in view of Official Notice. Haldeman discloses a method of navigating a lead within cardiac anatomy. Specifically, a lead 100 with a temperature sensor 106 is directed into the right atrium (see figure 1). The sensor measures the temperature of blood present in the right atrium as well as the temperature of blood leaving the targeted coronary sinus 114, such that the lead follows the trail of warmer blood towards the coronary sinus (par. 0047). Haldeman does not disclose, however, that the temperature value for blood in the right atrium should be averaged. However, the use of averaging values is notoriously old and well known in the art because it helps remove statistical outliers, including sensor malfunctions, and produces a value that best represents the temperature of an area of the right atrium, and not just at one particular spot. Therefore, the use of an average temperature value would have been obvious to one of ordinary skill in the art in order to provide a representative temperature value of an area of the right atrium.

13. Regarding claims 19 and 20, Haldeman discloses that the data from the temperature sensor is transduced into a user-perceivable representation indicative of a relative proximity between the lead and the coronary sinus (par. 0009). Furthermore,

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Haldeman discloses that the proximal transducer device 108 includes audible and visual feedback to the user.

***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

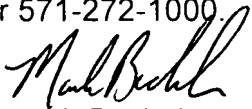
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram  
Examiner  
Art Unit 3766

  
Mark Bockelman  
Primary Examiner  
Art Unit 3766

EDB